K080105
p. 1 of 2

510(K) SUMMARY

[as required by 807.92(c)]

FEB 13 2009

A. 510k Number:

B. Applicant:

Company name: Chilecom Medical Devices Co., Ltd.

Address: 106 Boyi Road, Boluo County, Guangdong, China

Tel: +86-752-6282030

Fax: +86-752-6289386

Http://www.chilecom.cn

E-mail: chilecom@163.com

C. Proprietary and Established Names: Chilecom Medical Devices Co., Ltd.

D. Regulatory Information

1. Classification: Class II Device
2. Common Name: Tracheal tube
3. Product Code: **BTR (21 CFR 868.5730)**
4. Proprietary name: Endotracheal tube

E. Intended use

Endotracheal tube is intented for oral or nasal intubation and for airway management.

F. Device Description

Tracheal Tube uncuffed (chart 1) and with cuffed (chart uncuffed of Tracheal Tube only make up of body and connector。Tracheal Tube with cuffed make up of body and connector、cuff 、inflating tube、Pilot balloon 、Valve。Tracheal tube with a radius of curvature.。a line for x-radial through the body.。All tubes have an angle of bevel of 38±10° 。Length marks in centimeters measured from the patient end. The murphy eye on the side of the tube opposite the bevel. The tube machine end have the connector .It can connect the anesthesia machine or respiratory equipment. The inflating pilot balloon includes a valve fitting with a 6% (Luer) taper.

Each tracheal tube was contained in an individual pack .Sterilized by EOT. Single use only

G. Substantial Equivalence Information

1. Predicate device name

Predicate Device 1 – K042683 / Tracheal tube, Well lead endotracheal tube

2. Comparison with predicate

The Chilecom Tracheal tube device described in this *510K* is very similar in terms of design, materials and indications for use to three predicate devices already approved and marketed. There are no new safety concerns when compared to the already available predicate devices. For these reasons, we feel the Chilecom Tracheal tube fulfills all criteria to be found substantially equivalent to the predicate devices and should be cleared for marketing.

H. Standard / Guidance Document Referenced (if applicable)

ISO 5361:1999 Anaesthetic and respiratory equipment—Tracheal tubes and connectors

I. Sterility

-Sterilized by EO gas

-Sterile method: refer to validation report

-Self-life: 3 years

-Single use only.

J. Performance Characteristics (If/when applicable)

1. See the Exhibits.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Chilecom Medical Devices Company, Limited
C/o Mr. Brandon Choi
PATS Corporation
155 Flemington Court
La Mirada, California 90638

FEB 13 2009

Re: K080105
Trade/Device Name: Endotracheal Tube
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: October 28, 2008
Received: January 21, 2009

Dear Mr. Choi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for GYM

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Endotracheal Tube

Indications for Use: Endotracheal tubes is intended for oral or nasal intubation and for airway management.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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